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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 09/536,351      | 03/27/2000  | Sreenivasa Rao Damarla | 3900-003            | 3606             |

7590

09/02/2003

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EXAMINER

LEVY, NEIL S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 09/02/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

|                              |                               |
|------------------------------|-------------------------------|
| Application No.<br>09 536351 | Applicant(s)<br>DAMARLA et al |
| Examiner<br>NUTLEY           | Group Art Unit<br>1616 15     |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 5/30/03
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-12, 14-19, 23, 24 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-12, 14-19, 23 & 24 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

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Please follow new guidelines for amendments, and show all extant claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 9, 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Substantially free of organic solvents is stated to be supported by claim 2 and 17-19. They are ~~so~~ supported to the extent the words are the same, but no quantification is even hinted at. Page 9 does not have the word "substantially". No definition or quantification is disclosed. The meets and bounds ~~of the~~ claimed are in this respect undeterminable.

Claims 17, 19 does not further limit 14, as to Kleeberg, for what it teaches, it remains relevant as to categorizing materials; this is applicant's disclosure, applicant's remedy is to put the materials ~~in~~ issue into the claims. As to ~~milks~~; the same is true. See p. 9. Tween surfactant and cyclohexanone dissolved Azadirachtin.

Claims 1, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Carter et al 5124349.

The rejection of record is maintained. Neem oil, absent any showing to the contrary, meets applicants claim to a vegetable oil. The formulation have no added water, and in a humid environment, applicant's formulation would likewise, as claimed have no water but in fact, there would be some present. However carter extracts from dried seeds (col. 3, line 53-63) with present; less than 0.5, since when Carter adds

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water for testing comparison, .12% water is seen (Table V): See Table IV, par. 13.

Table II shows over 25% ~~AXADORAXHTIN~~ <sup>AZADIRACTIN</sup> @ over 28 days storage @ 55°C in sealed container's.

Claims, 1, 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dimetry et al '97 and Carter et al 5124349.

The rejection of record is maintained. Although applicant argues Dimetry has water, both references address Neem oil with Azadirachtinas pesticidal composition, and Carter teaches are to remove water to increase stability as shown above.

Applicant's arguments filed on 05/30/03 have been fully considered but they are not persuasive. Applicant's arguments have been addressed above as have applicant's explanations. Butler is no longer tenable as a 102 reference. However rejections are based on the language as generally recognized, of the claims, absent clear definitions in the specification to ~~vagant~~ <sup>Warrant</sup> interpreting the clear language to be limited to applicant's argued desires, ~~father~~, we see a basis for reconsideration based on exclusion with "consisting of" closed language, and reciting the surfactants.

Claims 1-3, 6-9, 14, 17, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by BLUM et al 5885600.

Cold extraction of Neem oil to provide solvent free Azadirachtins is disclosed, with added vegetable oil, citronellas, cedar wood (col. 3, line 9- line 4, col. 4). However surfactants were not added. Temperature, Humidity, PH is shown as elements of concern stability are maintained under nitrogen (col. 4, line 5-15). Non-ionic surfactants are they added, to permit later dilution as emulsions (col. 4, line 42-55) at time of use.

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Note that solvent is vegetable oil (col. 4, line 35-38). There is no water. Examples show no water, no organic solvent (Formulae B, C). So do claims (8, 11, 12). What are claimed are formulations, how they act is not seen as of patentable weight.

Claims 1-4, 6-12, 14-19, 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blum et al and Dimetry et al '97 in view of Butler et al 5352697.

Blum (above) teaches the instant compositions, and similar formulations, to solve the instant problem: sufficient amount and concentration of active components of insect control composition of natural ingredients, focusing on Neem tree leave, bark, seed extracts. Blum utilizes seed extracts free of added water free of applicant's organic solvents. Blum uses vegetable oil solvents. Surfactants are added, including the instant non ionic, (PEG dioleate of formula C). Blum maximizes content of actives, Azadirachtins, by cold press extraction, and shows as high as 50% Neem oil (col. 3, bottom), Thus, also providing high content of actives. Sealed containers are disclosed, as a means to prevent deterioration (col. 4, line 5-15). Since the instant compositions are disclosed had Blum submitted them to the instant stability tests, they would have met the required criteria. However, sesame oil was not mentioned.

Butler teaches the particular surfactant, inclusive of triglycerides, ethoxylated of sorbitan (col. 5, line 14-30), when preparing Azadirachtin derivatives (Example 10) as Neem seed extracts, of up to 50% (claim 21) Dimetry show sesame oil enhances Neem seed extracts insecticidal activity (p. 396, last paragraph).

Thus, the artisan would find it obvious to prepare particular ingredient combinations, and concentration and ratios of ingredients, depending upon the target

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species, desired number of applications, length to time for desired protection, ease of handling, target species, and degradation, for example.

The instant invention provides well known old art recognized compounds, with well known art recognized effects, applied by well known art recognized methods to achieve control over pest or crops as is well known in the art.

The primary reference discloses the essence of the instant invention as claimed, but does not specify each and every element of the instantly claimed compositions. However, the secondary references directed at same actives to solve the same problem of the primary reference do provide these additional elements.

It has not clearly been established by objective showing of some critical, unobvious and/or unexpected results that the particular form of active, carrier, or extract provides any greater level of prior art expectation as claimed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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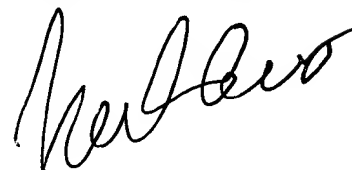
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is 308-2412. The examiner can normally be reached on Tuesday- Friday 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Levy/LR  
August 13, 2001

A handwritten signature in black ink, appearing to read "Neil S. Levy", is written over the typed name and title.

NEIL S. LEVY  
PRIMARY EXAMINER